



DEPARTMENT OF HEALTH & HUMAN SERVICES

J. BUTLER

HFA - 305

Food and Drug Administration  
Rockville MD 20857

9772 '00 DEC -6 P2:01

November 29, 2000

The Honorable Edward G. Staback  
House of Representatives  
Commonwealth of Pennsylvania  
Harrisburg, Pennsylvania 17120-2020

Dear Mr. Staback:

This is in response to your letter to the Secretary of Health and Human Services, on behalf of members of the hearing health profession, about a pending proposed rule to change federal hearing aid regulations.

In 1993, the Food and Drug Administration published an Advanced Notice of Proposed Rulemaking in the *Federal Register* to revise its regulations. One concern was the number of hearing aid purchasers who waived the current requirement for a hearing aid evaluation. Manufacturers, medical professionals, consumers, and hearing aid dispensers have commented on the rulemaking notice in writing and in meetings, but FDA has yet to publish a proposal.

Your letter has been added to docket #93N0372, which was set up to receive written comments on the 1993 notice. According to rulemaking procedures, neither FDA nor the Department of Health and Human Service can comment on what the proposal may or may not contain until after it publishes.

Sincerely,

Linda Gangloff  
Policy Analyst  
Executive Secretariat

93N-0372

C 4983  
/ANS

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November 8, 2000

Donna Shalala, Secretary  
The U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201


Dear Secretary Shalala:

I have been contacted by rightfully concerned members of the hearing health profession about the pending plans before you that would drastically change the manner in which hearing aids are distributed throughout our nation. Specifically, the changes that would permit audiologists to be the only hearing health tester and provider will not only adversely affect an entire industry of dedicated professionals but will also threaten the access now enjoyed by home-bound seniors and low income residents in need of hearing assistance.

I respectfully urge your refusal of these proposals on the grounds that they restrict access to care during a time when our government is seeking ways to widen health care options. Also, the trained professional that would be adversely affected deserve better. Patients who may not be able to afford or physically visit an audiologist rely upon the close personal contact that is provided through many of the caring staff of the hearing health care companies.

Madam Secretary, if there have been problems with the current system, I know of none in my district. However, I do fear problems if the proposed changes occur. I fear that the embarrassed or curious will not make the financial and public commitment that is needed to visit an audiologist. The present system seems to be working well and any changes to it, given their risk, should be based on much more substantial troubles.

Sincerely,

  
Edward G. Staback, Member  
115<sup>th</sup> Legislative District